

Purdue Statement in Response to Leak of 2015 Deposition of Dr. Richard Sackler

In August 2015, Dr. Richard Sackler was deposed in a lawsuit between Purdue Pharma and the Commonwealth of Kentucky. The litigation was subsequently settled, and Dr. Sackler's deposition, which had been sealed pursuant to a Court order, was never entered into evidence and was never relied on in any ruling by the court. Dr. Sackler's deposition is now the subject of a pending appeal to the Kentucky State Supreme Court.

The intentional leak of the deposition is a clear violation of the court's order and, as such, is regrettable. It shows contempt for the court's rules, which are in place to ensure the orderly conduct of the discovery phase of litigation, while still protecting the privacy of all parties' confidential information.

Despite the company's pending appeal to the Kentucky State Supreme Court, Purdue is commenting on the deposition only because of its unauthorized public disclosure, and out of concern that Dr. Sackler's testimony may be incorrectly and unfairly characterized.

The deposition principally involves events that took place more than 20 years ago.

During the deposition, Dr. Sackler described Purdue's efforts to adhere to all relevant laws and regulations and to appropriately reflect OxyContin's risks of abuse and addiction as the science of opioid pain therapy evolved over time.

OxyContin has been and continues to be approved by FDA for the treatment of patients suffering from severe chronic pain, including those with cancer and terminal illnesses, for whom alternative treatments are inadequate. As Dr. Sackler made clear in his deposition, OxyContin underwent a rigorous FDA approval process with clinical trials. The FDA has referred to that process as "the gold standard." OxyContin was tested, approved, and labeled based on a 12-hour dosing schedule, and since launch, the FDA has continued to approve OxyContin as a twice-a-day medicine.

OxyContin has always been classified and labeled as a Schedule II narcotic under the Controlled Substances Act, meaning the class of medicines with the highest risks of abuse and addiction. Purdue and FDA fully vetted the OxyContin launch labeling, with extensive revisions prior to FDA approval and labeling that included explicit warnings about abuse and misuse. When reports emerged in the early 2000's of widespread abuse and misuse of OxyContin, the warning label for the medicine was updated – including with a “black box” warning added in 2001— to reflect evidence of increased risk of abuse and addiction. Questions posed to Dr. Sackler at his deposition about whether Purdue should have performed certain abuse liability or addiction studies related to OxyContin did not take these facts into account.

Dr. Sackler's deposition also supports that the company accurately disclosed the potency of OxyContin to healthcare providers. Dr. Sackler takes great care to explain that from day one, the FDA-approved label made clear that OxyContin is twice as potent as morphine, meaning that to receive the same pain relief as morphine, OxyContin should be prescribed at half the dose as morphine. Purdue recognized OxyContin's greatest value was helping to address an unmet need of treating patients with chronic non-cancer pain. The company's determination to avoid emphasizing OxyContin as a powerful cancer pain drug was made out of a concern that non-cancer patients would be reluctant to take a cancer drug.

Dr. Sackler's statements in the deposition fully acknowledge the wrongful actions taken by some of Purdue's employees prior to 2002 as laid out in the 2007 Agreed Statement of Facts with the Department of Justice, and that the company has accepted full responsibility for those actions. Nothing in Dr. Sackler's deposition contradicts the 2007 Statement of Facts. Both the company and Dr. Sackler fully agree with and do not dispute the 2007 Agreed Statement of Facts.

In his deposition, Dr. Sackler notes that after Purdue Pharma's leadership was alerted to abuse and diversion of OxyContin beyond what was anticipated for a Schedule II opioid, the company acted decisively to address the problem, including developing the first opioid medication with properties intended to deter abuse, advocating for the use of prescription drug monitoring programs, and supporting access to naloxone.

Opioid abuse and addiction are one of the nation's top health priorities. Purdue Pharma remains committed to working collaboratively with all relevant parties to find comprehensive solutions to this public health crisis.